

REMARKS

The Examiner has objected to the listing of references in the specification on the grounds that such listing is not a proper Information Disclosure Statement.

However, the Examiner has failed to appreciate that that listing is not meant to be, and is not, an Invention Disclosure Statement. The sentence preceding the listing states:

"Other US patents of interest with respect to thermoresponsive materials are listed below:"

This is not an Information Disclosure Statement. Applicants appreciate that if any of these patents were not cited in a PTO Form 1449 and if a copy of same was not submitted to the office, there is no presumption that the Examiner has considered them.

Again, all applicant has done in the specification by listing these references is to provide more background to the invention disclosed.

The Examiner's rejection of claim 19 under 35 U.S.C. Section 102(b) for being anticipated by the Tovey US Patent No. 5,445,140, as this rejection may be attempted to be applied to amended claim 19, is respectfully traversed.

In support of this traverse, it is important to note that applicants are not claiming a temperature responsive shaped memory tip. Applicants are only claiming a tip, which has a temperature responsive hardness memory. In other words, applicants distal tip at the end of a distal tip portion of the catheter assembly, does not change its shape upon a change of temperature. Only the hardness/softness or durometer of the distal tip changes when the temperature of the distal tip passes through a critical temperature. In this respect, the distal tip will be harder at temperatures below a critical temperature and softer at a temperature above the

critical temperature.

Further in support of this traverse, it is noted that claim 19 has been amended to call for a distal tip portion, which has a temperature responsive hardness memory only tip.

Further, claim 19 has been amended to state:

--said distal tip not being a shape memory tip--.

Applicants submit that as so amended, claim 19 is not anticipated by the Tovey patent cited; and for that matter, not anticipated or rendered obvious by the Tovey patent, the Bley et al., US Patent No. 5, 762,630, or the Schroepel, US Patent No. 6,024,764.

The Examiner's rejection of claims 11, 12, 15 and 16 under 35 U.S.C. Section 103(a) for being unpatentable over Tovey in view of the Bley et al, US patent number 5, 762,630, and the Schroepel, US patent number 6,024,764, as these rejections may be attempted to be applied to the amended claims, is respectfully traversed.

In support of this traverse, it is to be noted that claim 11 has been amended to call for a distal portion, which is made of a plastic thermoresponsive material having a temperature responsive hardness memory only tip, and stating that the distal tip is not a shape memory tip. Furthermore, claim 11 calls for the tubular body to be coated with a jacket made of the plastic thermoresponsive material.

Applicants submit that such a catheter assembly is not at all suggested or disclosed by the references cited.

Again, while Tovey calls for an articulation providing hinge, which is harder at ambient temperature and which is tractable above a predetermined ambient temperature, Tovey does not disclose a distal tip of a distal tip portion, which is made of thermoresponsive hardness memory only material.

Nor does Tovey teach a distal tip, which changes form hard to soft when the tip is at a temperature above a predetermined temperature.

Rather, Tovey teaches a shape memory tip.

Furthermore, Tovey does not teach a temperature responsive hardness memory outer jacket on a tubular body.

Looking now at the Bley et al. patent, it is noted that this patent is directed to a stylet, which is made of a hardness memory material and can also include a shape memory material, which memory materials are thermoresponsive.

Note that while Bley et al. teaches that the catheter 111 made be made of a number of different materials, including a thermally softening material, Bley et al. does not teach a catheter tip made of a temperature responsive hardness memory material only. Nor does Bley et al. teach coating a tubular body with a thermoresponsive hardness memory material jacket as taught by applicant and as called for in amended claim 11.

Again, it cannot be emphasized enough that Bley et al. is directed to a stylet made of thermoresponsive hardness memory material.

Accordingly, Bley et al., by teaching a stylet made of thermoresponsive hardness memory material does not teach or suggest a distal portion of a catheter having a distal tip, which is made of thermoresponsive hardness memory only material.

The Examiner has cited the Schroepfel patent for its teachings of a shaped memory outer jacket. Again, applicants do not provide or have a shape memory material as an outer jacket.

The Examiner's rejection under 35 U.S.C. 103(a) of claim 13 and 14 for being unpatentable over the Tovey in view of the Bley et al. patent, as this rejection may be attempted to be applied to the amended Claims, is respectfully traversed.

First of all, in support of this traverse, applicants repeat and incorporates herein by reference the remarks made above with respect to claim 11 and claim 19.

In particular, claim 14 now calls for a distal portion having a distal tip, which has a temperature responsive hardness memory only tip. The claim also calls for the distal tip not being a shaped memory tip.

This claim further adds the feature that the distal portion of the tubular body is tapered and that the distal tip is welded or molded to the tapered distal portion.

It would appear that the Examiner intended to cite the Griep, US patent number 5,163,431 in combination with Tovey and Bley et al. against both claim 13 and claim 14.

Assuming this to be the case, and in support of the traverse of the rejection of claim 13 and claim 14, applicants submit that the combination of the temperature responsive hardness memory only tip combined with the other features, namely the tapered portion and the molding and welding on of the distal tip to the tapered portion and adding radiopaque material to the distal tip results in a combination of features which are not suggested by the references cited.

The Examiner's rejection of claims 17, 18, 20 and 22 under 35 U.S.C. Section 103(a) for being unpatentable over the Tovey patent in view of the Schroepel patent, as this rejection may be attempted to be applied to the amended claims, is respectfully traversed.

With respect to claim 17, it is noted that this claim as amended calls for the distal tip having a temperature response hardness memory only tip and states that the distal tip is not made of a shape memory material. Further, this claim calls for the tubular body being coated with a jacket made from the thermoresponsive hardness memory only material. None of these features are disclosed in the references cited. In particular, note that Schroepel is directed to a geometry

memory jacket and not to a temperature responsive hardness memory only jacket.

Claims 12, 16 and 22 are directed to the braided wire addition to the catheter assembly defined in the claim from which each of these claims depend and are considered to be directed to a narrower patentable combination. Applicants acknowledge that this feature alone is known from the older Stevens U.S. Patent No. 3,485,234 and Alston Jr. et al, U.S. Patent No. 4,425,919.

Claim 21 brings out the feature of a tubular body of a catheter assembly being coated with a jacket of plastic thermoresponsive hardness memory only material, which is harder at one temperature and softer at another temperature. Accordingly, applicant submits that claim 21 is not taught by, suggested by, or obvious from the references cited by the Examiner, such as the Schroeppel patent which is directed to a geometry memory jacket and not to a temperature responsive hardness memory only jacket...

In summary, applicants submit that the catheter assembly defined in the amended claims having a distal tip which is connected to a distal portion of a tubular body in a catheter assembly and which is made of a temperature responsive hardness memory material only, which does not have a temperature responsive geometry or shape memory tip, and/or which has a jacket of thermoresponsive hardness memory only material, is not at all disclosed or suggested by the references cited. Further, applicants submit that the combination of the feature of the memory hardness only material, the tapering of the distal tip portion and the molding or welding of the distal tip to the distal portion define an unobvious and patentable combination not taught by or suggested by the references cited.

Applicants submit that an earnest endeavor has been made to place this application in condition for allowance and an early and favorably action to that end

is requested.

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Date

Respectfully submitted,

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